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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,589	08/29/2003	Russell W. White	1030-0001	9154

34456 7590 05/16/2007

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EXAMINER	
ANDERSON, CATHARINE L	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/652,589	WHITE ET AL.	
	Examiner	Art Unit	
	C. Lynne Anderson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 February 2007 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.

In response to the applicant's argument that the prior art of record fails to disclose a membrane that is burst due to an increase in internal pressure, it is noted that swab applicators are well-known in the art to comprise a liquid encapsulated in a membrane that us burst by squeezing (i.e. increasing the internal pressure) the capsule.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mark (US 2003/0060746) in view of Beaudry (2004/0267180).

Mark discloses all aspects of the claimed invention with the exception of the first burstable membrane being configured to burst due to an increase in internal pressure. Mark discloses a self-contained substance application system, as shown in figure 3, comprising a support member 31 defining a first cavity and a second cavity. A first substance is located in the first cavity, and a second substance is located in the second cavity. A first burstable membrane 34 and second burstable membrane 35 enclose the cavities. An applicator 42 is attached to the support member, and conduit 39 indicated the location of the first cavity.

Beaudry teaches a substance application system having a burstable membrane encapsulating a substance. The membrane is burst by squeezing, as disclosed in paragraph [0023], which causes an increase in the internal pressure of the membrane, causing the membrane to burst.

It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the application system of Mark with the burstable membrane of Beaudry, to obviate the need for glass materials in the application system of Mark.

With respect to claim 2, the support member 31 comprises a first support member 32 and a second support member 33, which each have an open end and a closed end, and are affixed to one another at their respective closed ends 36, as shown in figure 3.

With respect to claim 3, crimp 36 isolates the first and second cavities.

With respect to claim 4, Mark discloses all aspects of the claimed invention with the exception of the first caving having a larger volume than the second cavity. It would

have been obvious to one of ordinary skill in the art at the time of invention to make one cavity larger than the other to allow for different amounts of medicament to be applied to the patient.

With respect to claim 5, the support member 31 has a linear configuration, as shown in figure 1. The support member 31 is tubular, as disclosed in paragraph [0024], and therefore has a circular cross section.

With respect to claim 6, the support member 31 defines a mouth of the first cavity at a first distal end, and a mouth of the second cavity at the second distal end, as shown in figure 3. A second applicator 41 is attached to the second mouth, and has a different appearance than the first applicator 42.

Claims 7, 9-10, 13-16, 19-20, and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crane (6,811,341) in view of Beaudry (2004/0267180).

With respect to claim 7, Crane discloses all aspects of the claimed invention with the exception of the first burstable membrane being configured to burst due to an increase in internal pressure. Crane discloses a method of removing an application system from a package, operating a delivery mechanism to initiate release of a substance from a cavity by bursting the membrane of the cavity, releasing the substance to a porous applicator tip, and applying the substance, as described in column 6, line 42, to column 7, line 5. The application system is single use and therefore discarded after use, as disclosed in column 5, lines 5-6.

Beaudry teaches a substance application system having a burstable membrane encapsulating a substance. The membrane is burst by squeezing, as disclosed in paragraph [0023], which causes an increase in the internal pressure of the membrane, causing the membrane to burst.

It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the application system of Crane with the burstable membrane of Beaudry, to obviate the need for a plunger in the application system of Crane.

With respect to claim 9, the support member is a tube, and therefore has a round cross section. A plunger is depressed to operate the delivery mechanism, as disclosed in column 6, lines 49-60.

With respect to claim 10, the substance is combined with an initiator to convert the monomer to a polymer, as disclosed in column 6, lines 61-65.

With respect to claim 13, Crane discloses a substance application system, as shown in figure 11, comprising a cavity formed from a support member 1008. The cavity contains a substance 1020 comprising a fast polymerizable liquid monomer, as disclosed in column 11, line 39. An expulsion orifice 1032 is configured to release the substance, and an applicator tip 1026 is configured for depositing an adhesive film on a surface.

With respect to claim 14, the fast polymerizable liquid monomer comprises cyanoacrylate, as disclosed in column 5, lines 30-40.

With respect to claim 15, a delivery mechanism 1006 initiates release of the contained substance by rupturing a burstable membrane 1022, 1024, as shown in figure 11.

With respect to claim 16, a second cavity is provided comprising a second substance 1030, the second substance being different from the first substance, as disclosed in column 11, lines 43-44.

With respect to claim 19, the method comprises locating first and second substances and attaching an applicator to the support member, as disclosed in column 6, lines 28-39.

With respect to claim 20, the opening of the first cavity is enclosed by a burstable member 1024, as shown in figure 11.

With respect to claim 22, the support member and attached applicator are sealed in a container, as shown in figure 10.

With respect to claim 23, the support member is a tube, and therefore has a round cross section. The support member partially defines the first and second cavities, as shown in figure 11.

With respect to claim 24, the first cavity is isolated from the second cavity, as shown in figure 11.

With respect to claim 25, an indicator, first end 1032, identifies the location of the first cavity 1002, as shown in figure 11.

With respect to claim 26, the support member has a long axis, as shown in figure 11, and is a tube, which has an elliptical cross section.

With respect to claim 27, the first substance comprises a polymerizible liquid monomer, which is associated with an initiator, as disclosed in column 6, lines 61-65.

With respect to claim 28, a burstable seal 1022 keeps the first substance in the first cavity, as shown in figure 11. A package contains the support member, protecting it from contamination, as disclosed in column 10, lines 33-35.

With respect to claim 29, an indicator, first end 1032, identifies the location of the first cavity 1002, as shown in figure 11.

With respect to claim 30, a second seal 1012 keeps the second substance in the second cavity, as shown in figure 11. A sterile applicator 1026 is attached to the support member 1008.

With respect to claim 31, a plurality of packages are contained in a box, as disclosed in column 10, lines 33-35.

Claims 8, 11-12, 17, 21, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crane (6,811,341) in view of Beaudry (2004/0267180), and further in view of D'Alessio et al. (6,595,940).

With respect to claim 8, Crane, as modified by Beaudry, discloses all aspects of the claimed invention with the exception of squeezing the support member along a major axis to operate the deliver mechanism. D'Alessio teaches a substance application method involving squeezing the support member along a major axis to operate the delivery mechanism, as described in column 7, lines 40-45 to provide a simple yet effective application system, as disclosed in column 4, lines 19-20. It would

therefore be obvious to one of ordinary skill in the art at the time of invention to apply the substance of Crane by squeezing the support member, as taught by D'Alessio, to provide a simple yet effective application system.

With respect to claims 11 and 21, Crane discloses all aspects of the claimed invention with the exception of a second applicator tip. D'Alessio teaches a second applicator tip for application of the second substance, as disclosed in column 8, lines 17-23. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the support member of Crane with a second applicator tip, as taught by D'Alessio, to provide for separate application of the second substance.

With respect to claims 12, 17, and 32, Crane discloses all aspects of the claimed invention with the exception of an antiseptic agent. D'Alessio teaches an application system for applying cyanoacrylate to a patient, and discloses an initiator that comprises an antiseptic agent to promote healing of the wound site, as disclosed in column 11, lines 41-57. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the initiator of Crane with an antiseptic agent, as taught by D'Alessio, to promote healing of the wound site.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crane (6,811,341) in view of Beaudry (2004/0267180), and further in view of Mark (US 2003/0060746).

Crane, as modified by Beaudry, discloses all aspects of the claimed invention with the exception of the applicator tip being cotton. Crane discloses the support

member comprises plastic, as described in column 10, lines 55-56. Mark teaches an application system having a cotton applicator tip, as described in paragraph [0023], as a suitable material for applying a treatment material to a wound. It would therefore be obvious to one of ordinary skill in the art at the time of invention to make the applicator tip of Crane of cotton, as taught by Mark, to provide a suitable material for applying a treatment material to a wound.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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May 11, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER